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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/510,680 | 07/20/2005 | Maria Prat Quinones | 09605.0003 | 4960 |

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EXAMINER

CHU, YONG LIANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/510,680 | PRAT QUINONES ET AL. | |
| | Examiner | Art Unit | |
| | Yong Chu | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 30 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-26, 30, 32-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-26, 30, 32, and 33 are amended, claims 27-29 are cancelled, and claim 34 is added by amendment filed on 8 October, 2004. Therefore, claims 1-26, and 30-34 are currently pending in the instant application.

Priority

This application is a 371 of PCT/EP03/03786, filed on 11 April 2003. Acknowledgement is made of Applicant's claim for Spain Patent Application 200200889 under 35 U.S.C. § 119(a-d), filed on 16 April 2002.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

Lack of Unity Requirement

Claims 1-26, and 30-34 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that “special technical features” mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

“The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

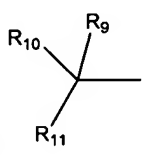
(i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or

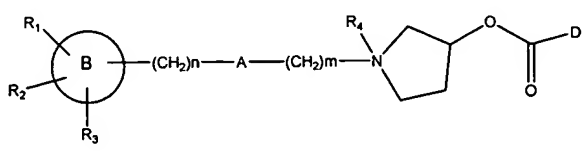
(iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,...

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: Claims (1-10, 12-20, 23-24)(in part wherein A is $-\text{CH}_2-$, $-\text{CH}=\text{CR}^7-$, $-\text{CR}^7=\text{CH}-$,

$-\text{CR}^7\text{R}^8-$ or $-\text{CO}-$; D is  wherein R^7 - R^{11} defined according to claim 1), 26, and

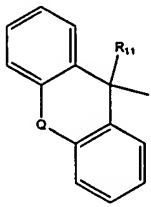
32-34 are drawn to a compound or a composition which contains at least one

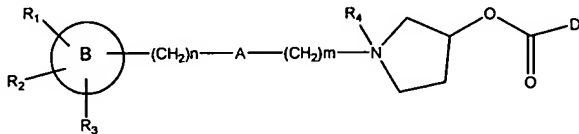
compound of formula I  according to claim 1. If

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this group is elected, Applicant is requested to elect a single species for search purposes. ***Applicant is also requested to list all the compounds in claims 18-20, and 23-24 which fit in this group according to the instant grouping definition of A and D.*** This group is subject to further restriction, if elected.

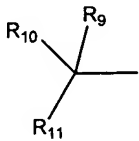
Group II: Claims (1-9, 11-20, 23-24)(in part wherein **A** is $-\text{CH}_2-$, $-\text{CH}=\text{CR}^7-$, $-\text{CR}^7=\text{CH}-$, -

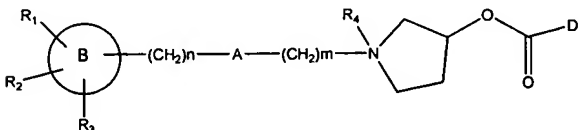
CR^7R^8- or $-\text{CO}-$; **D** is  wherein R^7 - R^8 , and R^{11} are defined according to claim 1), 26, and 32-34 are drawn to a compound or a composition which contains at least

one compound of formula I  according to claim

1. If this group is elected, Applicant is requested to elect a single species for search purposes. ***Applicant is also requested to list all the compounds in claims 18-20, and 23-24 which fit in this group according to the instant grouping definition of A and D.*** This group is subject to further restriction, if elected.

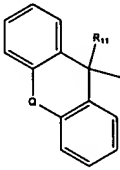
Group III: Claims (1-10, 12-20, 23-24)(in part wherein **A** is $-\text{O}-$, $-\text{S}-$, $-\text{S}(\text{O})-$, and $-\text{S}(\text{O})_2-$

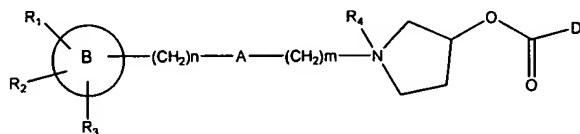
; **D** is  wherein R^9 - R^{11} defined according to claim 1), 26, and 32-34 are drawn to a compound or a composition which contains at least one compound of formula I

 according to claim 1. If this group is elected,

Applicant is requested to elect a single species for search purposes. ***Applicant is also requested to list all the compounds in claims 18-20, and 23-24 which fit in this group according to the instant grouping definition of A and D.*** This group is subject to further restriction, if elected.

Group IV: Claims (1-9, 11-20, 23-24)(in part wherein **A** is $-\text{O}-$, $-\text{S}-$, $-\text{S}(\text{O})-$, and $-\text{S}(\text{O})_2-$;

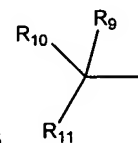
D is  wherein **R¹¹** defined according to claim 1), 26, and 32-34 are drawn to a compound or a composition which contains at least one compound of formula I



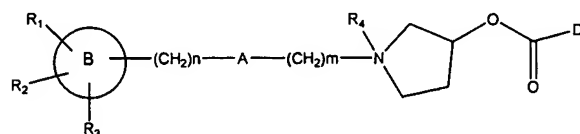
according to claim 1. If this group is elected,

Applicant is requested to elect a single species for search purposes. ***Applicant is also requested to list all the compounds in claims 18-20, and 23-24 which fit in this group according to the instant grouping definition of A and D.*** This group is subject to further restriction, if elected.

Group V: Claims (1-10, 12-20, 23-24)(in part wherein **A** is $-\text{NR}^7-$; **D** is

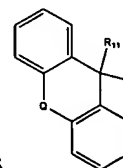


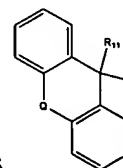
wherein **R⁷** and **R⁹-R¹¹** defined according to claim 1), 26, and 32-34 are drawn to a compound or a composition which contains at least one compound of formula I

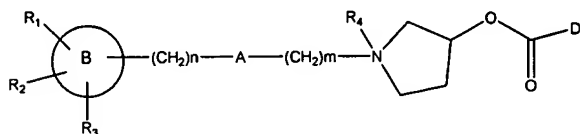


according to claim 1. If this group is elected,

Applicant is requested to elect a single species for search purposes. ***Applicant is also requested to list all the compounds in claims 18-20, and 23-24 which fit in this group according to the instant grouping definition of A and D.*** This group is subject to further restriction, if elected.



Group VI: Claims (1-9, 11-20, 23-24)(in part wherein **A** is $-\text{NR}^7-$; **D** is  wherein R^7 and R^{11} defined according to claim 1), 26, and 32-34 are drawn to a compound or a composition which contains at least one compound of formula I



according to claim 1. If this group is elected,

Applicant is requested to elect a single species for search purposes. ***Applicant is also requested to list all the compounds in claims 18-20, and 23-24 which fit in this group according to the instant grouping definition of A and D.*** This group is subject to further restriction, if elected.

Group VII: Claims 21-22 are drawn to a process for the preparation of the compound of formula I defined in claim 1 using an intermediate of formula (II). If this group is elected, Applicant is requested to elect a single species to make for search purposes.

Group VIII: Claim 25 is drawn to a process for the preparation of the compound of formula I defined in claim 1 using an intermediate of formula (III). If this group is elected, Applicant is requested to elect a single species to make for search purposes.

Group IX: Claims 30-31 are drawn to a method for treating a subject afflicted with a pathological condition or disease susceptible to amelioration by antagonism of M3 muscarrinic receptors, comprising administering to said subject an effective amount of a compound as claimed in claim 1. If this group is elected, Applicant is requested to elect a single disease for search purposes.

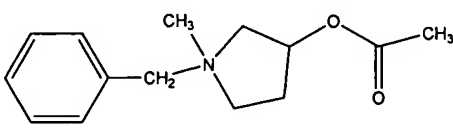
In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. 1.475(a) **Groups I-IX** lack unity of invention since under 37 CFR 1.475:

Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Groups I-IX** is . This

technical feature is not a special technical feature, because it fails to define a

contribution over the compound  of a prior art by

Clarkson et al. *Journal of Neurochemistry* **1992**, 59(2), 695-700. Therefore, claims 1-26, 30, 32-34 are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a

whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on any examination of the claimed subject matter.

Because the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product, a process for the manufacture of said product, or a method of use.

Furthermore, with respect to **Groups I-IX**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

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The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention.

The claims directed to a single method of preparation and a single method of use will be examined along with the elected invention so long as it is commensurate in scope therewith.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even if the restriction requirement is traversed (37 CFR 1.143).

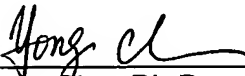
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed Yong Chu whose telephone number 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

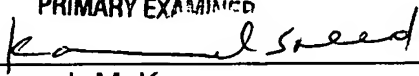
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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